



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

8387 '97 AUG 12 NO 05
DEC 26 1996

Mr. Ronald Koss
Great Circles, Inc.
P.O. Box 1250
Montpelier, Vermont 05601

Dear Mr. Koss:

This is in response to your letter of October 9, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making statements of nutritional support for your products, Recovery Power Foods Supplemental Drink Mix and Recovery Power Foods Supplemental Nutrition Bar.

It is unclear from your submission if these products are dietary supplements. A dietary supplement is defined in section 201(ff) of the act. In part, a dietary supplement may not be "represented for use as a conventional food or as a sole item of a meal or the diet" (section 201(ff)(2)(B)). Further, the definition of a dietary supplement in section 201(ff)(2)(C) stated that the product must be labeled as a dietary supplement. The statements of identity of your products, Recovery Power Foods Supplemental Drink Mix and Recovery Power Foods Supplemental Nutrition Bar, do not clearly identify these products as dietary supplements. Therefore, if these products in the context of the information on the label or in the labeling represent themselves as conventional foods, they are subject to the labeling requirements of section 403(q) of the act and 21 Code of Federal Regulations (21 CFR) 101.9 and other applicable provisions of the act.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, New England District Office, Office of Compliance, HFR-NE200

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

cc:

HFA-224 (w/incoming)

HFS-22 (CCO, KCarson)

HFS-456 (r/f, Miles, Moore)

HFS-450 (r/f)

HFD-304 (Aronson)

HFS-600 (Reynolds)

r/d: C:\miles:12/11/96:C:\Miles\suppl\49361

Initial R. Moore: 12/16/96

f/d: C:\miles:12/20/96:C:\Miles\suppl\49361

October 9, 1996

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OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

'96 OCT 22 P3:47

Office of Special Nutritionals, HFS-450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Sir or Madam,

Notice is hereby given pursuant to the requirements of proposed Section 101.93 of Title 21, Subpart F, Code of Federal Regulations and Section 403(r)(6) (21 U.S.C. 343(r) (6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement Recovery Power Foods Supplemental Drink Mix and Recovery Power Foods Supplemental Nutrition Bar.

Recovery Power Foods Supplemental Drink Mix will be marketed with these statements of nutritional support on or about November, 1996. The text of the statements of nutritional support are as follows as follows:

- *all natural nutrition to support wellness and health recovery*
- *to help replenish and maintain normal nutrient reserves and support healthy immune function, digestion, energy needs and vitality*
- *immune system support*
- *promotes healthy intestinal flora*

Recovery Power Foods Supplemental Nutrition Bar will be marketed with these statements of nutritional support on or about November, 1996. The text of the statements of nutritional support are as follows:

- *all natural nutrition to support wellness and health recovery*

These products will be promoted in brochures in which these statements of nutritional support will be printed:

- *Many other nutrients (in addition to high quality protein, carbohydrates and essential fatty acids) such as selenium, chromium, magnesium, taurine, Vitamin C, Vitamin E, Vitamin A, natural mixed carotenoids...all work together to provide the best in wellness and health recovery support.*
- *High quality protein supports tissue repair and the production of essential enzymes, hormones and antibodies.*

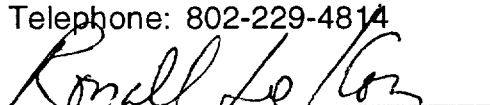
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- *Brown rice syrup solids and fructose are excellent energy sources. Fructose is known to cause a more gradual change in blood sugar and insulin relative to other simple sugars.*
- *Canola, rice bran oil, docosahexaenoic acid and structured lipids together support the normal function of all tissues, the immune system and energy needs.*
- *Medium chain triglycerides provide an easily absorbed and highly utilizable source of energy.*
- *L-Glutamine amino acid providing nutrititional support for the digestive system and tissue repair.*
- *Zinc Picolinate: Antioxidant nutrient helping to protect the body from free radicals and oxidative stress.*
- *N-acetylcysteine: important antioxidant nutrient shown to support the immune system*
- *All natural nutritional support for wellness and health recovery*
- *Recovery Power Foods help to replenish and maintain normal nutrient reserves shown to support healthy immune function, digestion, energy needs and vitality.*
- *Docosahexaenoic (DHA) is an extremely valuable natural fatty acid shown to support immune function.*

I hereby certify that the information presented and contained in this notice is complete and accurate and that our company has substantiation that the statements of nutritional support that are the subject matter of this notice is truthful and not misleading.

Very truly yours,

Ronald Koss
Great Circles, Inc.
P.O. Box 1250
Montpelier, VT 05601
Telephone: 802-229-4814



Ronald Lee Koss
Vice-President